## **Allovedic** Remedies

# **American Formulary**

August 12, 1998



Office of Special Nutritonals (HFS-450) Center for Food Safety and Applied Nutrition Food and Drug Administration 200 C Street, SW Washington, DC 20204

1873 '98 AUG 21 P12:48

Re: Notification for statements on Dietary Supplements

In compliance with DSHEA regulations, we are providing notice to the Food and Drug Administration of a new dietary supplement label with structure/function claim(s):

Brand Name:

Allovedic Remedies<sup>TM</sup>

Product Name:

Probiotic with B Complex

Structure/Function Claim:

Supports the Maintenance of Healthy Intestinal Flora and

Helps to Metabolize Nutrients

The distributor of the product is:

viil G. Reag

American Formulary, Inc.

P.O. Box 50777

Provo, UT 84605-0777

1-800-350-3305

Attached is a sample of the printed label for this product for your reference, which includes a bolded and boxed FDA disclaim statement if a claim is made.

Submitted by:

Neil G. Reay

Vice President

60702

### American

### Remedies TM

## Formulary

#### FDA Notification for Statements on Dietary Supplements

August 12, 1998

#### **Label Sample**

Suggested Use: Take one tablet with water two times a day. Supports the maintenance of healthy intestinal flora and helps to metabolize nutrients.\*

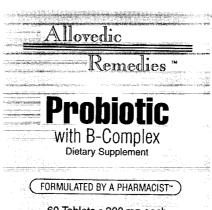
American Formulary's Allovedic Remedies" combines the technology of today's medical science (Allopathy) with the traditional knowledge from ancient health systems (such as Ayurveda). A whole new class of supplements has emerged.

Keep all supplements out of the reach of children. Consult a health care professional if taking prescription medications, or if pregnant or nursing. Store in a cool, dry place.

This bottle is sealed with a printed outer film seal and an inner freshness seal. Do not use if either seal is broken.

\*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.





	Na atau
Tablets • 300	mg each
a de la companya de	
prompt grant to a constant	British to State Control of the Cont

Suppleme Serving Size: 1 tablet	9	
Amount per servin	ıg: %DV	20-909
Thiamine (Vitamin B1)	3 mg 200%	<b>1</b> 8 m
Riboflavin (Vitamin B2)	3 mg 175%	Y, INC., Provo, L Use by 7/31/03
Niacin (as niacinamide)	40 mg 200%	7 8 8
Vitamin B6 (pyridoxine)	1 mg 50%	5. ∯.
Folic acid	300 mcg 75%	ا ﷺ ج
Vitamin B12 (cyanocobalamin)	4.5 mcg 75%	Mag (
Pantothenic acid	4 mg 40%	S
Lactospore* (Lactobacillus sporogenes):	38 mg * * 200 million organisms	AMERICAN FORMULARY, INC., Provo, UT 84605-0777  Lot #: Use by 7/31/03
* * Daily value not established		istributed by:
Lactospore® is a registered tradema	rk of Sahinsa Cornoration	istrid